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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,359	09/10/2004	Johan Bernard Ubbink	115808-504	5698

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
08/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/507,359	UBBINK ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/22/2008 has been entered.

Claim Objections

2. Claims 1, 3, and 11 are objected to for "cm3". "3" is expected to be the exponent of "cm". Correction is required.

Use Claims

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 10 provides for the use of the pellets as a delivery system, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 4 is indefinite for "105 to 1014 viable micro-15 organisms". It is unclear what is meant by "105 to 1014 viable micro-15 organisms". It is not clear what the applicant regards the invention.

8. Claim 10 is also indefinite for "the use of". It is unclear what is meant by "the use of" since there are no steps provided as expected for use claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

10. Claims 1, 4-7, 9, and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Casas-Perez (US 5,480,641; hereinafter R1).

11. R1 discloses methods and product for direct feed microorganisms such as Lactobacillus reuteri delivered in pellets (compacted whey particles) (Abstract).

12. R1 teaches coating the palletized whey particles with lyophilized L. reuteri cells suspended in oil (col. 3, lines 55-57) or the suspension of L. rerteri in oil is mixed with whey powder and then the mixture is compressed into pellets (compressed whey particles) or tablets. (Col. 3, lines 62-65). Given that oil is impermeable to moisture, the pellet will be impermeable to moisture.

13. The pellets may have different sizes (Col.4, lines 10-20) for instance particles which go through mesh 8 (2.38 mm) but retained by mesh 20 (0.84 mm) or particles going through mesh 0.25 inch (6.35 mm) but retained by mesh 8 (2.38 mm). It is clear that pellets having size between 2.38 mm and 0.25 inch would inherently possess volume as presently claimed.

14. R1 teaches that whey pellets may contain $5x10^7$ to about 10^8 cells/g whey (Col. 4, lines 25-27).

15. Given that the cells are lyophilized (below water activity of 0.3) and the suspending agent and binder is oil and the supporting matrix is whey powder, the water activity of less than 0.3 will be inherent to the pellets.

16. R1 teaches using 1—15 lbs/sq. in pressure to produce the compacted pellets (Col. 4, lines 10-11)

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1and 3-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okonogi et al. (US 4888171; hereinafter R2) in view of Klapwijk et al. (EP 0 298 605; hereinafter R3) and Van Lengerich (WO 99/48372; hereinafter R4).

19. R2 discloses a granular product containing dried viable microorganism cells, which has been protected against permeation of environmental moisture and atmospheric oxygen (Col. 2, lines 36-39). It also teaches of the materials used in the formation of the core of their product (Col. 3, lines 9-23). The coating of their product is explained in terms of the composition and function. It teaches of the use of the binding materials for coating the product in order to protect it against permeation of the environmental moisture and atmospheric oxygen. It further explains the use of shellac or zein for enteric coating (Col. 5, lines 17-34; Col. 8, lines 33-46). It specifies the granular product to have a mean diameter of 1.5 mm (Col. 9, lines 1-2). Assuming a spherical shape, the mean granule volume is calculated to be 1.77 mm^3.

20. R2 gives details of making a granular product containing dried viable bacterial cells, the product being substantially free of water (Claims 1 and 4). It also mentions that the water content of the core material is preferably as low as possible, less than 5% (w/w) (Col. 3, lines 22-23).

21. R2 discloses the viable count of lactic acid bacteria in their product to be 14 x 10^8 cells/g. The survival rate has been calculated to be 98% (Col. 9, lines 6-13). It is claimed that the cell survival rate in their product exceeds that of the conventional product during prolonged storage periods (Abstract, Table 1, Table 2, Table 3).

22. R2 teaches of the materials to be used for composing the core of their product. They clearly teach of materials such as sugar or sugar/starch composition (fillers) which can be pelletized. Use of dried viable microorganisms (functional ingredient) in the core is disclosed (Col. 3, lines 9-23). Use of binding and plasticizing materials (fats/oils, propylene glycol fatty acid ester) is further disclosed and examples of binding materials are given (Col. 3, lines 30-34). Use of lubricant is disclosed in experiment 2 (Col. 6, formulation table).

23. R2 explain the use of sugar/starch compositions to be used for the core of their product. It mentions that almost anything edible that can be pelletized may be used in the core of their product including palletized dried viable microorganisms (Col. 3, lines 13-23).

24. R2 discloses the concept of coating their granular product in order to protect it from environmental moisture and atmospheric oxygen. (Col. 2, lines 36-39). It further explains the use of various coating materials, which provide palatable taste, flavor, color and enteric coating. (Col. 5, 17-34; Col. 8, lines 33-46).

25. R2 teaches making particles by pelletizing various ingredients including saccharides, and acid crystals. They mention that particles of such materials and any other edible material may be prepared by pelletizing these materials. For instance, dried

viable microorganisms, a pelletized product of such powder mixes may be used as the core material.

26. While the examples of R2 teach amounts of microorganisms outside the scope of the present claims, these are just a few preferred embodiments of R2. A fair reading of the reference as a whole does not limit the amount of microorganisms. It would have been obvious for one of ordinary skill in the art to choose the amount of microorganisms, including that presently claimed, depending on the end use of the granular product as well as to produce a less expensive product.

27. R2 is silent on the water activity (a_w) of their pellets.

28. R3 discloses the process of making supported lactic acid bacterial compositions where the water activity of the supported flora products is 0.3 or less, particularly 0.2 or less. They also mention that improved storage life is provided with water activity values 0.15 or less (Page 3, lines 47-49).

29. R4 discloses a product that contains encapsulated live organisms. The matrix composition of his invention comprises a plasticizer and a substantial amount of a free flowing mixture (page 3, lines 8-15). The coating of the pellets is discussed in example 2 and 3 (page 35 and 36). He discloses the dimensions of the product where the extruded rope may have a cross sectional diameter 0.5 mm to about 3 mm. Assuming an average pellet diameter of 1.75 mm, the pellet volume is calculated to be about 2.8 mm^3

30. R4 describes the product to be non-expanded, non-puffed, and substantially non-cellular. It is also mentioned that the starch is substantially ungelatinezed, and not

substantially destructurized or dextrinized. Specific densities of the products are disclosed to be about 0.8 to 1.5 g/cm^3 (Page 33, lines 8-13).

31. R4 teaches of the use of the pellets as food or their incorporation into foods, nutraceuticals and pharmaceuticals . A variety of foods having various moisture levels are mentioned. His product comprises at least one component of the food e.g. yogurt which can contain nonfat dry milk, or gelatin, or lactose (Page 33 line 14 to page 34 line 16).

32. R4 teaches of the incorporation of pellets containing live mircro-organisms into various foods where the food and the pelleted product share at least one ingredient. He mentions that the encapsulated product may be incorporated, with or without grinding, into foods for human or animal consumption. The foods, which are exemplified do share, at least, one component with the granulated product (Page 33, lines 14-23 and page 34, lines 1-2).

33. It would have been obvious to one of ordinary skill in the art , at the time the invention was made, to modify the teachings of R2 by using the teachings of R3 and R4 to make the probiotic delivery system of the instant application. One would have done so to receive the benefits of a product which could be used as a delivery system for dried viable organisms. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success in making a probiotic delivery system with characteristics outlined in the instant application.

Response to Arguments

Applicants' arguments have been thoroughly reviewed and considered.

1. Applicants argue that R1 discloses pellets having higher number of microorganism than the presently claimed pellets.

a. The examiner agrees that although the examples of R2 (Okonogi) teach amounts of microorganisms outside the scope of the presently claimed. However, these are just a few preferred embodiments of R2. A fair reading of the reference as a whole does not limit the amount of microorganisms. It would have been obvious for one of ordinary skill in the art to use any amount of microorganisms, including that presently claimed, depending on the end use of the granular product as well as to produce a less expensive product.

2. Applicants argue that Klapwijk is directed to preparing bacterial compositions in bread making and that the examples by Klapwijk clearly only teach processes for preparing cell concentrate mixtures or processes for incorporating these mixtures into bread dough.

a. Klapwijk teaches the preparation of *Lactobacillus* species (NRRL B-18368), incorporated into a rye flour matrix dried to less than 1% moisture resulting in a water activity of 0.2. This is a core containing *Lactobacilli* which has a low water activity with a shelf life of several months. He mentions that his invention is suitable for the application of other lactic acid bacteria such as *Pediococci*, *Streptococci*, *Leuconostoc* and

Bifidobacteria. His invention has application in food, animal feed and agricultural industries. His invention is not limited to bread making (Page 2, lines 3-4). Klapwijk is clearly teaching the importance of reduced water activity on the shelf life of the *Lactobacilli* in a delivery system. On the other hand, Klapwijk is teaching that the invention to other micro-organisms such as *Bifidobacteria*, *Streptococci* etc. Since these bacteria are not normally involved in bread baking, the invention is not limited to bread baking as alleged by the applicants.

3. Applicants argue that a need is recognized to provide stable probiotics or probiotics delivery system that can be added to food products having an Aw (water activity) value above optimal for probiotics to survive and that they have found surprisingly that by compacting dried microorganisms together with matrix, which may consist of dried food material, and by coating the pellets with a food grade moisture barrier, Applicants could obtain an excellent stability over storage time.

a. A closer look at the concepts taught by the references used in the rejections clarifies the fact that a delivery system composed of food materials, the type of species of micro-organisms which could be incorporated into the delivery system, the importance of water activity and the limits of water activity for prolonged shelf life, the importance of coating the palletized product to provide moisture and air barrier, the coating materials, the number of coatings which could be possibly applied are all disclosed by these references.

Further, note that while R3 and R4 do not disclose all the features of the present claimed invention, R3 and R4 are used as teaching reference, and therefore, it is not

necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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